

GOODYS COOL ORANGE- acetaminophen, aspirin and caffeine powder

Lil' Drug Store Products, Inc

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Goody's® Cool Orange

Drug Facts

Active ingredients (in each powder)	Purposes
Acetaminophen 325 mg	Pain reliever
Aspirin (NSAID*) 500 mg	Pain reliever
Caffeine 65 mg	Pain reliever aid

* nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - backache
 - toothache
 - menstrual cramps
 - muscular aches
 - colds

Warnings

Reye's syndrome

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

Allergy alert

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4 powders in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if

you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Caffeine warning

This product contains caffeine. Limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

Do not use

- if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking

- A prescription drug for diabetes, gout, or arthritis
- The blood thinning drug warfarin

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away
- you experience any of the following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- any new symptoms appear
- ringing in the ears or a loss of hearing occurs

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than directed** (see overdose warning)
- adults and children 12 years of age and over: place 1 powder on tongue every 6 hours, while symptoms persist. Drink a full glass of water with each dose, or may stir powder into a glass of water or other liquid.
- do not take more than 4 powders in 24 hours unless directed by a doctor.
- children under 12 years of age: ask a doctor.

Other information

- store below 25°C (77°F)

Inactive ingredients

colloidal silicon dioxide, flavors, guar gum, mannitol, microcrystalline cellulose, sucralose

Questions or comments?

1-866-255-5197 goodyspowder.com

Manufactured by Medtech Products Inc., Tarrytown, NY 10591

PRINCIPAL DISPLAY PANEL - 2 Packet Carton

**ORANGE
FLAVOR**

FAST PAIN RELIEF

Goody's®

**COOL ORANGE
EXTRA
STRENGTH**

**ACETAMINOPHEN • ASPIRIN (NSAID) / CAFFEINE
PAIN RELIEVER / PAIN RELIEVER AID**

Goody's®

**COOL ORANGE
HEADACHE POWDERS**

**2 SEALED
POWDER PACKS**

**Lil'
Drug Store®**



TAMPER EVIDENT FEATURE: DO NOT USE IF PACKET IS DAMAGED OR OPEN.

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Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives • facial swelling • shock • asthma (wheezing)

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LIFT PANEL FOR CONTINUED DRUG FACTS

Drug Facts (continued)

- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Caffeine warning: This product contains caffeine. Limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

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Questions or comments? 1-866-255-5197 goodyspowder.com

TO OPEN CHILD-RESISTANT PACKAGE

www.goodyspowder.com



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1-877-507-6516 M-F (8 AM-4:30 PM CST) 97142C-US-01-14





GOODYS COOL ORANGE

acetaminophen, aspirin, and caffeine powder

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:66715-530 1(NDC:630 29-663)
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Aspirin (UNII: R16CO5Y76E) (Aspirin - UNII:R16CO5Y76E)	Aspirin	500 mg
Caffeine (UNII: 3G6A5W338E) (Caffeine - UNII:3G6A5W338E)	Caffeine	65 mg

Inactive Ingredients

Ingredient Name	Strength
Silicon Dioxide (UNII: ETJ7Z6XBU4)	
Sucralose (UNII: 96K6UQ3ZD4)	
Guar Gum (UNII: E89I1637KE)	
Mannitol (UNII: 3OWL53L36A)	
Cellulose, Microcrystalline (UNII: OP1R32D61U)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor	ORANGE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66715-530 1-3	2 in 1 CARTON		
1		1 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	03/01/2014	

